PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gopi M. VENKATESH et al.

Application No.: 10/619,924 Confirmation No.: 7145

Filed: July 15, 2003 Group Art Unit: 1618

For: CONTROLLED RELEASE POTASSIUM CHLORIDE TABLETS Examiner: TRAN, Susan T.

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OK TO ENTER: /S.T./ **SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. §1.312**

Please amend the above-captioned application as follows:

Amendments to the Specification begin on page **2** of this paper.

Amendments to the Claims begin on page **3** of this paper.

Remarks begin on page **9** of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0014] with the following paragraph:

[0014] FIG. 2 shows plasma levels of potassium following oral dosing - comparison between 20 mEq controlled release potassium chloride tablets of Example ~~11~~10, which do not disperse into granules on contact with water or body fluids, versus reference standard (K-Dur) of equal strength.

Replacement paragraph [0014], without markups:

[0014] FIG. 2 shows plasma levels of potassium following oral dosing - comparison between 20 mEq controlled release potassium chloride tablets of Example 10, which do not disperse into granules on contact with water or body fluids, versus reference standard (K-Dur) of equal strength.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Previously Presented) A process for preparing a controlled release tablet of potassium chloride comprising:

(a) microencapsulating potassium chloride crystals with an inner membrane comprising ethylcellulose by coacervation or phase separation to form potassium chloride microcapsules;

(b) coating said potassium chloride microcapsules with an outer membrane comprising a plasticized polymer to form compressible coated microcapsules;

(c) preparing a compressible blend comprising said compressible coated microcapsules, microcrystalline cellulose, and colloidal silicon dioxide; and

(d) compressing said compressible blend into tablets,

wherein the tablet hardness is at least about 14 kP, the friability of the tablet does not exceed about 0.3%, and the tablet exhibits a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

after 2 hours, about 30% to about 50% of the total potassium chloride is released;

after 4 hours, about 60% to about 75% of the total potassium chloride is released; and

after 8 hours, not less than 80% of the total potassium chloride is released,

wherein said plasticized polymer comprises a polymer selected from the group consisting of ethylcellulose, polyvinylpyrrolidone, and hydroxypropyl methylcellulose,

wherein said colloidal silicon dioxide is present in an amount of from about 0.1% to about 0.3% by weight of said tablet,

wherein said outer membrane coating comprises from about 0.5% to about 5.0% by weight of said compressible coated microcapsules, and

wherein said compressible blend is substantially free of lubricants.

2. (Previously Presented) The process of claim 1, wherein said compressible blend further comprises a disintegrant.

3. (Previously Presented) The process of claim 2 wherein said disintegrant is present in an amount of from about 0.5% to about 5.0% by weight based on the tablet weight.

4. (Canceled)

5. (Previously Presented) The process of claim 1 wherein said plasticized polymer comprises ethylcellulose and said coating step comprises coating said potassium chloride microcapsules with an aqueous dispersion of ethylcellulose.

6. (Original) The process of claim 5 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate.

7. (Previously Presented) The process of claim 1 wherein said microcrystalline cellulose comprises not more than about 15% by weight of said tablet.

8. (Previously Presented) The process of claim 1 wherein the inner membrane comprises ethylcellulose having a viscosity between about 90 cps and about 110 cps.

9. (Original) The process of claim 8 wherein said ethylcellulose forming the inner membrane comprises between about 8% and about 20% by weight of said potassium chloride microcapsules.

10. (Canceled)

11. (Original) The process of claim 3 wherein said compressible blend further comprises from about 0.1% to about 1.0% of a surfactant based on the weight of said tablet.

12. (Original) The process of claim 1 wherein said plasticized polymer comprises a plasticizer selected from the group consisting of dibutyl sebacate, diethyl phthalate, triacetin, triethyl citrate,

polyethylene glycols of different molecular weights and mixtures thereof.

13. (Original) The process of claim 12 wherein said plasticizer comprises from about 2% to 40% based on the weight of the plasticized polymer.

14. (Canceled)

15. (Previously Presented) The process of claim 1 wherein said plasticized polymer comprises hydroxypropyl methylcellulose and polyethylene glycol 400.

16. (Canceled)

17. (Previously Presented) The process of claim 1 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate, and wherein said compressible blend comprises about 0.1% to 0.2% by weight colloidal silicon dioxide and not more than about 15% by weight of said microcrystalline cellulose.

18. (Previously Presented) The process of claim 17, said compressible blend further comprising a disintegrant present in an amount of from about 0.5% to about 3% by weight of said compressible blend.

19. (Original) A controlled release potassium chloride tablet prepared by the process of claim 1.

20. (Currently Amended) A controlled release potassium chloride tablet comprising

a) a plurality of microcapsules wherein said microcapsules comprise a potassium chloride crystal, an inner membrane on said crystal comprising ethyl cellulose, and an outer membrane surrounding said inner membrane comprising a plasticized polymer;

b) colloidal silicone dioxide; and

c) microcrystalline cellulose,

wherein the tablet hardness is at least about 14 kP, the friability of the tablet does not exceed about 0.3%, and the tablet exhibits a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

after 2 hours, about 30% to about 50% of the total potassium chloride is released;

after 4 hours, about 60% to about 75% of the total potassium chloride is released; and

after 8 hours, not less than 80% of the total potassium chloride is released,

wherein said plasticized polymer comprises a polymer selected from the group consisting of ethylcellulose, polyvinylpyrrolidone, and hydroxypropylmethylcellulose,

wherein said colloidal silicon dioxide is present in an amount of from about 0.1% to about 0.3% by weight of the total tablet weight,

wherein said microcapsules comprise from about 0.5% to about 5.0% by weight of said outer membrane, and

wherein said ~~compressible blend~~tablet is substantially free of lubricants.

21. (Previously Presented) The controlled release potassium chloride tablet of claim 20 wherein said inner membrane comprises between about 8% and about 20% by weight of said microcapsules.

22. (Canceled)

23. (Canceled)

24. (Original) The controlled release potassium chloride tablet of claim 20 wherein said tablet further comprises a disintegrant.

25. (Currently Amended) The controlled release potassium chloride tablet of claim 24 wherein said disintegrant is selected from the group consisting of sodium starch glycolate, croscarmellose sodium, and cross-linked polyvinylpyrrolidone.

26. (Original) The controlled release potassium chloride tablet of claim 20 wherein the potassium chloride is present in an amount effective for the treatment of potassium deficiency in humans by oral administration.

27. (Canceled)

28. (Original) The controlled release potassium chloride tablet of claim 20 wherein said plasticized polymer comprises ethyl cellulose and diethyl phthalate.

29. (Previously Presented) A method of treating potassium deficiency in a subject in need of potassium, comprising administering to the subject an effective amount of the controlled release potassium chloride tablet of claim 20.

30. (Canceled)

31. (Previously Presented) The controlled release potassium chloride tablet of claim 20, wherein said microcrystalline cellulose is present in an amount of not more than about 15% by weight of the total tablet weight.

32. (Previously Presented) The process of claim 2, wherein said disintegrant is selected from the group consisting of sodium glycolate, croscarmellose sodium, cross-linked polyvinylpyrrolidone, and combinations thereof.

33. (Previously Presented) The controlled release potassium chloride tablet of claim 20, further comprising a disintegrant and optionally a surfactant.

34. (Previously Presented) The controlled release potassium chloride tablet of claim 20, wherein said plasticized polymer comprises a plasticizer selected from the group consisting of dibutyl sebacate, diethyl phthalate, triacetin, triethyl citrate, polyethylene glycols of different

molecular weights, and mixtures thereof.

35. (Previously Presented) The controlled release potassium chloride tablet of claim 20, wherein said plasticized polymer comprises from about 2% to 40% of the plasticizer.

REMARKS

Applicants have corrected an inadvertent error in the Amendment Under 37 C.F.R. § 1.312 filed October 9, 2009. Applicants incorrectly referenced paragraph [0013] rather than paragraph [0014] in the "Amendments to the Specification" section at page 2 of the Amendment.

For the Examiner's convenience, the Applicants have reiterated the additional amendments requested in the previous Amendment.

The amended claims presented herein include the Examiner's amendments to the claims. Applicants have further amended claim 20 to recite "wherein said tablet is substantially free of lubricants," in the final wherein clause, rather than "wherein said compressible blend is substantially free of lubricants," as in the Examiner's Amendment. (emphasis added). This amendment is supported by the specification at page 5, paragraph [0009]. Applicants further note that the term "tablet" has antecedent basis in claim 20, unlike the term "compressible blend". Applicants have also amended claim 25 to include the term "and" before the last item in the list of disintegrants. Applicants believe that no new matter has been added by way of these amendments.

Applicants respectfully request that the Examiner enter the foregoing amendments prior to issuance.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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Respectfully submitted,
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